Supreme Court, U.S.
FILED

No. 04-781

NOV 29 2004
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In The Supreme Court of the United States

XECHEM INTERNATIONAL, INC.,

Petitioner,

v.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR WRIT OF CERTIORARI WITH APPENDIX

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1. Whether United States Constitutional Eleventh Amendment state sovereign immunity bars an action in United States Federal District Court to correct inventorship of an issued United States patent and to change ownership by way of corrected inventorship of an issued United States patent.

II. PARTIES TO THE PROCEEDING IN THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Petitioner:

XECHEM, INTERNATIONAL, INC.

Respondents:

UNIVERSITY OF TEXAS

M.D. ANDERSON CANCER CENTER

BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM

III. CORPORATE DISCLOSURE STATEMENT

Petitioner Xechem International, Inc. is a publicly held Delaware corporation.

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VII. STATEMENT OF THE BASIS FOR JURISDICTION

(i) Date the Order Sought to be Reviewed was Entered: August 31, 2004

(ii) Dates of Orders Respecting Rehearing, and Date and Terms of Orders Granting Extension of Time to File Petition for Certiorari: Not Applicable.

(iii) Statement Respecting Rule 12.5 Concerning Cross-Petitions: Not Applicable.

(iv) Statement of the Statutory Provision Believed to Confer on the Supreme Court of the United States Jurisdiction to Review Writ of Certiorari: 28 USC § 1254:

Cases in the courts of appeals may be reviewed by the Supreme Court by the following methods:

> (1) By writ of certiorari granted upon the petition of any party to any civil or criminal case, before or after rendition of judgment or decree;
>
> * * *

(vi) Statement of Notification Required by Rule 29.4 (b) and (c):

Rule 29.4 (b): Not Applicable

Rule 29.4(c): Not Applicable.

VIII. CONSTITUTIONAL PROVISIONS, TREATIES, STATUES, ORDINANCES AND REGULATIONS INVOLVED

1. Constitutional Provisions.

United State Constitution, Amendment 5:

> No persona shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

United States Constitution, Amendment 14, section 1:

> All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

United States Constitution, Amendment 11

> The judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

2. Federal Statutes.

35 U.S.C. § 256 ¶2:

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all parties and assignees, with proof of the facts and other such requirements as may be imposed, issue a certificate correcting such error.
>
> The error omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

3. Federal Rules of Civil Procedure.

F.R.C.P. 12(b)

> How Presented. Every defense, in law or fact, to a claim for relief in any pleading, whether a claim, counterclaim, cross-claim, or third-party claim, shall be asserted in the responsive pleading thereto if one is required, except that the following defenses may at the option of the pleader be made by motion: (1) lack of jurisdiction over the subject matter, (2) lack of jurisdiction over the person, (3) improper venue, (4) insufficiency of process, (5) insufficiency of service of process, (6) failure to state a claim upon which relief can be granted, (7) failure to join a party under Rule 19. A motion making any of these defenses shall be made before pleading if a further pleading is permitted. No defense or objection is waived by being joined with one or more other defenses or objections in a responsive pleading or motion. If a pleading sets forth a claim for relief to which the adverse party is not required to serve a responsive pleading, the adverse party may assert at the trial any defense in law or fact to that claim for relief. If, on a motion asserting the defense numbered (6) to dismiss for failure of the pleading to state a claim upon which relief can be granted, matters outside the pleading are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as proved in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56.

IX. STATEMENT OF THE CASE

A. BASIS FOR FEDERAL JURISDICTION IN THE COURT OF FIRST INSTANCE

This case involves a claim for correction of inventorship in issued United States patents, and for a change or transfer of ownership rights in these patents as based on corrected inventorship. This case also necessarily involves a claim for deprivation of the due process rights of petitioner granted by the Fifth Amendment to the United States Constitution, as made applicable to the States by the Fourteenth Amendment thereto. Petitioner invoked the jurisdiction of the United States District Court below pursuant to 35 U.S.C. § 256 to correct inventorship, and to change ownership by way of corrected inventorship, of United States patents Nos.: 5,777,205 and 6,107,333 (the "'205" and "'333" patents). On March 19, 2003 The Southern District of Texas dismissed Petitioner's suit to correct patent inventorship and ownership rights in these patents for failure to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6), and held that the Eleventh Amendment to the United States Constitution bars such a suit under § 256 in Federal District Court. The United States Court of Appeals for the Federal Circuit affirmed the District Court's decision on August 31, 2004.

The question presented for review is whether the Courts below erred by holding that Constitutional Eleventh Amendment state sovereign immunity bars an action against a state entity in Federal District Court to correct inventorship of an issued United States patent and to change ownership of said patent by way of corrected inventorship, and further whether such a bar would be a deprivation of Petitioner's Constitutional due process rights to it's patent property ownership.

B. STATEMENT OF THE FACTS

Petitioner Xechem International, Inc. ("Xechem") originally brought this lawsuit for correction of inventorship of the '205 and '333 patents which claim new formulations for paclitaxel and paclitaxel analogs, pursuant to 35 U.S.C. § 256 in addition to other state-based causes of action.

Paclitaxel is a well-known anti-tumor agent that has been approved by the Food and Drug Administration ("FDA") for the treatment of ovarian and breast cancer. Currently, is available for humans in only one formulation approved by the FDA, of which an example is Taxol® manufactured by Bristol Myers-Squibb Co. Taxol® contains the active paclitaxel as the active ingredient which is responsible for anti-tumor activity, and is stabilized in ethanol and Cremopher® E1 which is used as a drug carrier to overcome poor water solubility problems associated with paclitaxel. Cremopher® E1 is a trade name for a polyoxylylated caster oil product that is considered highly toxic, a suspected carcinogen, and makes paclitaxel hard to administer in that, among other things, it easily dissolves plasticizers from PVC based infusion bags.

Petitioner Xechem is a biopharmaceutical company and Respondents, The University of Texas M.D. Anderson Cancer Center ("MDA") and Board of Regents of the University of Texas System ("UT") (collectively "UT/MDA") are branches of the University of Texas, an agency of the State of Texas. Xechem's President and CEO is Ramesh C. Pandey, Ph.D. ("Dr. Pandey").

Xechem has a Scientific Advisory Board that discusses Xechem's scientific research projects on an ongoing basis. Dr Elias Anaissie, M.D., formerly an employee and agent of Respondents UT/MDA from about

August 1984 to August 1996, has been a member of Xechem's Scientific Advisory Board since at least about April, 1994, and as a regularly discusses Xechem's research projects with other Board members. At an Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) annual meeting, Dr. Pandey and Dr. Anaissie conceived of and invented a new formulation for paclitaxel. Thereafter, with possibilities of collaborative research endeavors in mind between Xechem and Dr. Anaisse and colleagues at UT/MDA to produce a commercial product of the inventive new paclitaxel formulation, Dr. Anaissie was provided with a quantity of paclitaxel from Xechem. Dr. Anaissie subsequently discussed this invention with his colleague at UT/MDA, Dr. Borje S. Andersson, and provided Dr. Andersson with the Xechem paclitaxel and instructions to prepare the inventive new formulation by solubilizing it in dimethylacetamide ("DMA"), polyethylene glycol ("PEG") and an aqueous lipid emulsion, Intralipid, and to perform stability and shelf-life studies on the new formulation with the idea of collaborating with Xechem in producing a new commercial paclitaxel formulation.. Later, at a meeting on or about April 6, 1995, Dr. Pandey met with Drs. Anaissie and Andersson at UT/MDA in Houston, Texas during which collaborative research efforts to develop a commercial new paclitaxel formulation were further discussed, and the three met again on or about August 17, 1995 for the same purpose. On or about September 18, 1995, Dr. Andersson contacted Xechem in New Jersey and accepted Xechem's offer to become part of Xechem's Cancer Research Advisory Panel to participate in the evaluation of preclinical data, and for the design of future clinical studies of Xechem-originated pharmaceutical agents. In accepting this offer, Dr. Andersson requested that Xechem provide him with a confidentiality agreement, and further requested discussion of the specifics of various Xechem related projects including Xechem's invention of now Paclitxel formulations. Following this, on December 13, 1995,

Xechem entered into a Sponsored Laboratory Study Agreement with Respondents UT/MDA in which Xechem financed all of the research and provided all of the active ingredient paclitaxel and relevant HPLC analysis methods with the purpose to produce a new paclitaxel formulation.

In early 1996 Xechem had a draft patent application prepared based on the collaborative work of Xechem and UT/MDA which claimed Dr. Pandey and Dr. Anaissie's invention/conception of a parenterally administered paclitaxel formulation of paclitaxel in DMA/PEG/Intralipid. The patent application claimed Dr. Pandey's invention conception of a paclitaxel-analog formulation comprising a paclitaxel analog, DMA, PEG and Intralipid. The draft application was then forwarded to UT/MDA under the terms of the collaborative Sponsored Research Agreement between Xechem and UT/MDA.

UT/MDA next responded by repeatedly and adamantly insisting that the sole inventor was Dr. Andersson, and threatened to, *inter alia*, cease all progress on the collaborative research work if Xechem did not agree. Based on UT/MDA's affirmations, Dr. Pandey mistakenly agreed with UT/MDA's ultimatum that Andersson was the sole inventor.

Following these events, without Dr. Pandey's or Dr. Anaissie's knowledge, UT/MDA commissioned the preparation of a patent application on its own by it's law firm using confidential Xechem materials, information and the inventions of Drs. Pandey and Anaisse, and filed the application on June 28, 1996 which named Borje S. Andersson as the sole inventor as to all the claimed subject matter, and which later issued as '205 patent, and ultimately the '333 patent which recites and claims essentially the same subject matter as the '205 patent. These patents claim Dr. Pandey's and Dr. Anaissie's invention of paclitaxel and

paclitaxel analog formulations as set out above, and Dr. Pandey's invention of the novel formulation comprising paclitaxel analogs disclosed under confidence to Andersson.

While still mistaken as to correct inventorship of the patents in suit, Xechem entered into a Patent and Technology License Agreement (the "License Agreement") with UT/MDA in which Xechem became an exclusive licensee of the '205 patent. UT/MDA subsequently terminated the Agreement alleging that Xechem was insolvent, or was insolvent a period of years prior to Xechem filing it's suit. Along with this allegation, UT/MDA accused Xechem of infringing the '205 patent, and presumably the later issued '333 patent.

C. PROCEDURAL HISTORY

Approximately one month after receiving Respondent's letter terminating the Agreement, Xechem filed a lawsuit in which Xechem sought, *inter alia,* a declaratory judgment stating that Xechem is not infringing upon the '205 and '333 patents and to correct inventorship and ownership of these patents.[1]

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[1] The lawsuit was filed in the United States District Court District of New Jersey. While the case was pending in New Jersey, Defendants filed a Motion to Dismiss Xechem's Second Amended Complaint for lack of federal jurisdiction, lack of personal jurisdiction, failure to state a claim upon which relief may be granted, and improper venue. Alternatively, Defendants moved to transfer venue to the Southern District of Texas. The New Jersey court denied Defendants' Motion to Dismiss on grounds of personal jurisdiction and improper venue, but agreed that venue was more properly laid in the Southern District of Texas. By order entered February 21, 2002, the case was transferred to the Southern District of Texas. In light of the transfer, the New Jersey court declined to consider Defendants' challenge based on Eleventh Amendment Immunity grounds.

Pursuant to 35 U.S.C. § 256, Xechem requested that the Court determine the correct inventorship of the '205 and '333 patents and that it correct the patents either by adding Dr. Pandy and/or Dr. Yankov and/or Dr. Anaissie as joint inventors, or alternatively, by removing Dr. Andersson as an inventor and adding in place thereof Dr. Pandey and/or Dr. Yankov and/or Dr. Anaissie as joint inventors. Xechem further requested that the Court issue an order directing the Commissioner of Patents and Trademarks to correct the inventorship of the '205 and '333 patents accordingly. .

Respondents moved to dismiss Xechem's claims based on Eleventh Amendment immunity, contending that as arms of the State they enjoy sovereign immunity and cannot be sued in federal court, which Xechem disputed.

Finding that Eleventh Amendment immunity bars Xecham's claims for a determination and correction of inventorship pursuant to Section 256, and that Respondents had not waived their Eleventh Amendment immunity by applying for and obtaining a United States patent, the District Court dismissed Petitioner's action on March 13, 2003, pursuant to Fed. R. Civ. P. 12(b)(6).

Petitioner appealed the United States Court of Appeals for the Federal Circuit, which issued an opinion affirming the order of the District Court. Petitioner now seeks review of this Court on the basis that the issues presented are of fundamental importance to the integrity of the United States patent system, and to the deprivation of individual property interests in inventorship and ownership rights in United States patent properties without being afforded Constitutional due process. The issues presented in this appeal have not previously been decided by this Court.

X. SUMMARY OF ARGUMENT

Eleventh Amendment sovereign immunity does not bar a Section 256 patent inventorship correction action in federal district court as it is not applicable to such an action. The State of Texas is not the owner of the '205 and '333 patents, or at least not the sole owner of these patents, and congressional intent and § 256 does not require the State of Texas' consent to proceed with this correction action to determine inventorship rights and ownership rights of others in the '205 and '333 patents. Further, notwithstanding whether the Eleventh Amendment applies to this action, the State of Texas by appearing in the United States Patent and Trademark Office, a quesi-judicial United States agency, in applying for and prosecuting to issuance the '205 and '333 patents and declaring through its employee and agent, Dr. Borje Andersson, to be the sole and correct inventor of said patents, expressly consented to be sued in federal district court for correction of inventorship under the United States Patent Act 35 U.S.C. § 256, thereby waiving Eleventh Amendment immunity. Additionally, by the State of Texas' acceptance of the constitutional and congressional grant of the '205 and '333 patents, it received a gift or gratuity from the United States government under the condition that the State of Texas be subject to all United States laws and regulations pertaining to the issuance of a valid U.S. patent grant, including true and correct inventorship and ownership of patents.

Furthermore, patent inventorship determination and inventorship correction can only be accomplished in Federal District Court which has exclusive jurisdiction in these matters. To deny Petitioner access to the only forum which can determine and order patent inventorship correction, and ownership correction, is a fundamental deprivation of Petitioner's Constitutional due process rights to its personal property.

In summary, Petitioner Xechem is not barred by Eleventh Amendment Immunity from an action in federal district court to correct inventorship of the '205 and '333 patents, and placing these patents and foreign counterparts thereof in the name of the true inventors and owners of these patents.

XI. ARGUMENT

A. Petitioner's action in United States Federal District Court for a determination of correct inventorship of the '205 and '333 patents, to correct inventorship of these patents, and for patent ownership determination should not be barred by the Eleventh Amendment

Petitioner has sought a request for determination of inventorship and correction of inventorship of the '205 and '333 patents under 35 U.S.C. § 256 in Federal District Court, the only forum which is equipped with jurisdiction to make such determinations, and to vest ownership rights of the '205 and '333 patents in the true inventors and owners of these patents, or, alternatively, the correct joint inventors and owners. Corresponding case law interpreting § 256 not only permits a suit in Federal District Court for the determination of correct inventorship, but federal district courts have exclusive jurisdiction over such claims under 28 U.S.C. § 1338(a) because they "arise under" the United States patent laws. *See e.g., FFOC Company v. Invent A.G.*, 842 F. Supp. 642, 659 (E.D.M. 1994), (citing *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1468 (Fed. Cir. 1989)). No other forums are supplied with jurisdiction to hear and decide these issues, and certainly not state courts such as suggested by the Federal Circuit's opinion.

Section 256 not only allows for a determination of joint or co-inventorship, but also for complete substitution of inventors as long as the true inventors are without deceptive intent. *Perspective Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 F. Supp. 2d 69, 70 (D. Mass. 1998) (*citing Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551, 1556 (Fed. Cir. 1997)). *See also e.g., The University of Colorado Foundation Inc. v. American Cyanamid Company*, 196 F.3d 1366, 1324 (Fed. Cir. 1999) and *The University of Colorado Foundation, Inc. v. American Cyanamid Company*, 105 F. Supp. 2d 1164, 1185 (D. Colorado 2000) (the District Court held that the true inventors of an improved formulation for a prenatal multivitamin had no deceptive intent, and that their names could be substituted for that of the named inventor regardless of whether the initial naming of the named inventor occurred as a result of deception or was simply an innocent mistake, citing *Stark v. Advanced Magnetics, Inc.*, (119 F.3d at 1555)); see also, *Heineken Technical Services B.V. v. Darby*, 103 F. Supp. 2d 476, 479 (D. Mass 2000). However, where inventorship may be corrected to save the validity of a patent, inequitable conduct or deceptive intent in omitting a true inventor will render an otherwise valid patent forever unenforceable, notwithstanding the absence of deceptive intent on the part of the true inventor and owner of the patent, thereby irreversibly damaging or destroying the true owner's or co-owner's property rights. See, for example, *Frank's Casing Crew & Rental Tools, Inc. v. Vincent*, 292 F.3d 1363, 1376 (Fed. Cir. 2002).

Contrary to the Federal Circuit's opinion, it is respectfully submitted that Petitioner's request for the District Court to determine inventorship and to correct inventorship under Section 256 is not barred by Eleventh Amendment immunity, which is not applicable to patent inventorship correction. For example, as stated in *College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board*, 527 U.S. 666, 686-87 (1999) "[s]tates *cannot*

form an interstate compact without first obtaining the express consent of Congress; the granting of such consent is a gratuity. So also, Congress has no obligation to use its Spending Clause power to disburse funds to the states; such funds as gifts" (emphasis added.) Similarly, states cannot create a patent, let alone correct inventorship of an invalid patent or decide when corrective inventorship actions are required– only Congress can. So it is not the consent of a state but the consent of Congress that is bestowed by a patent, and the correction of a patent (*i.e.* the issuance of a valid enforceable patent with correct inventorship) is solely within the purview of Congress, and not a state defendant. Congress, in turn, has conferred jurisdiction upon the Federal Courts pursuant to Section 256 to correct inventorship as needed. The Eleventh Amendment simply is inapplicable in such circumstances, especially when the State of Texas is not an owner of these patents, or is a co-owner with no right of accounting from other co-owners with respect to corrected patent inventorship.

Title 35 U.S.C. § 256, Correction of named inventor, provides:

> Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error. The error of omitting inventions or naming persons who are not inventor shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section.

Section 256 further provides,

> The court before which such matter is called in question may order correction of the patent on notice and hearings of all parties concerned and the Director shall issue a certificate accordingly (emphasis added).

According to Section 256's clear terms, the PTO's jurisdiction to correct the inventorship of an issued patent extends only to situation where all parties have consented to correction. As the Fourth Circuit held in *Iowa State University Foundation, Inc. v. Sperry Rand Corp.*, 444 F.2d 406, 410 (4th Cir. 1971):

> In short, where the Commissioner is asked to correct innocent errors of misjoinder or non joinder, all parties must apply for relief to comply with the requirements of the first and second paragraph. Notice and an opportunity for all parities to be heard are the only requisites for judicial action that Congress expressly prescribed.

Accord, Dee v. Aukerman, 625 F. Supp. 1427, 1429 (S.D. Ohio 1986) (Section 256 requires only notice and a hearing in order for a district court to order correction of a patent. Consent of all parties is not required as in 37 C.F.R. Sections 1.324 and 1.20(b) for correction by certain administrative proceedings before the Commissioner).

The United States Court of Appeals for the Federal Circuit agreed with *Sperry - Rand* in *Stark v. Advanced Magnetics, Inc.*, 119 F.3d 1551 (Fed. Cir. 1997). *Stark* involved an interlocutory appeal from a judgment of the Massachusetts district court to determine under what

circumstances correction of inventorship is permissible. In siding with the Fourth Circuit the Federal Circuit held:

> In *Iowa State University Foundation, Inc. v. Sperry Rand Corp.*, 444 F.2d 406, 170 USPQ 374 (4th Cir. 1971), the Fourth Circuit addressed the question of whether consent of all parties is necessary to state a claim for correction in the district court. That court concluded properly that such consent is not necessary...In fact, inventorship contest by definition will lack consent of all inventors. The court then recognized, therefore, that the only procedural prerequisites to maintain a correction action in district court are notice and an opportunity for all parties to be heard.

citing *MCV, Inc. v. King – Seely Thermos Co.*, 879 F.2d 1658, 1570, (Fed Cir. 1989) ("Section 256 prescribes only one prerequisite to judicial action; all parties must be given notice and an opportunity to be heard. If that is done there is subject-matter jurisdiction in the district court over a dispute raising solely a joint inventorship issue among contending co-inventors").

The district court had exclusive jurisdiction over Petitioner's claim to correct the inventorship of the patents at issue, and those claims do not require the State's consent to proceed – all that is needed is notice and an opportunity to be heard. As such, Eleventh Amendment immunity is not a bar to such action, and the District Court incorrectly dismissed Petitioner Xechem's inventorship correction action.

B. State entity Respondents expressly waived its Eleventh Amendment sovereign immunitywhen it voluntarily invoked the jurisdiction of the quasi-judicial United States Patent and Trademark Office and accepted the benefits and protections of a federal patent grant

Respondents voluntarily sought and acquired a federal patent - a benefit, gift and gratuity offered by the United States Constitution and Congress with the condition that the true and correct inventors be named and that United States patents are solely enforceable in Federal Court. It is submitted that Respondents cannot choose to enjoy the benefits and exclusivity conferred by United States patents and simultaneously hide behind the Eleventh Amendment to prevent suit to correct inventorship in federal court, and to deprive the true owners or co-owners of their patent property rights without due process of law.

Three Supreme Court decisions recently address federal jurisdiction with respect to states' Eleventh Amendment immunity. See *College Savings Bank v. Florida Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 119 S. Ct. 2219, 144 L. Ed. 2d 605 (1999); *Florida Prepaid Postsecondary Educ. Expense Bd. v. College Savings Bank*, 527 U.S. 627, 636, 119 S. Ct. 2199, 144 L. Ed. 2d 575 (1999); *Seminole Tribe v. Florida*, 517 U.S. 44, 72, 116 S. Ct. 1114, 134 L. Ed. 2d 252 (1996). Even though the Supreme Court held that Congress could not unilaterally abrogate a state's sovereign immunity under its Article I powers, *Florida Prepaid* 527 U.S. 627, nor does a state waive its sovereign immunity merely by engaging in ordinary business activities or activities regulated by a federal statute, the Court acknowledged that a state may waive immunity by constructive waiver under certain circumstances. *See College Savings*, 527 U.S. 666, 686, 119 S. Ct. 2219 (1999).

Sovereign immunity is waived by constructive waiver where Congress clearly expresses its intent to waive sovereign immunity coupled with the state's clear expression of its intent to waive immunity. *See, MCI Telecommunications Corp. v. Illinois Bell Telephone Co.*, 222 F.3d 323, 340 (7th Cir. 2000), cert. denied, 2001 U.S. LEXIS 897 (citing *Pennhurst State School and Hospital v. Halderman*, 451 U.S. 1, 17, 101 S. Ct. 1531, 67 L. Ed. 2d 694 (1981)). Accordingly, the first threshold issue is whether Congress has "[spoken] with a clear voice such that the states may exercise their choice to waive their immunity knowingly, cognizant of the consequences of their participation." *Id.* In *MCI*, the Court found that Congress had "unmistakably" conditioned a state's participation in the federal regulatory scheme upon consent to federal court review. *See Id.* at 341. In an analogous manner, a Federal patent granting system inclusive of patent validity regulations and corrective actions is a Federal regulatory scheme, and states' participation in this scheme in arguing for and acquiring patents is conditioned upon the states' consent to Federal Court review, for example, in correction of invalid patents under 35 U.S.C. § 256.

The second issue necessary to show constructive waiver is that the state "unequivocally" expresses its intent to waive Eleventh Amendment immunity. *MCI, Telecommunications Corp. v. Public Service Commission*, 216 F.3d 929, 935 (10th Cir. 2000) (citing) *College Savings*, 527 U.S. at 680-81, 119 S. Ct. 2219). "A state can declare its intent to submit to suit by impliedly or constructively waiving its immunity if the declaration is clear and altogether voluntary." *Id* (citing generally *College Savings Bank*, 527 U.S. 666, 119 S. Ct. at 2223). "Voluntary consent exists where Congress bestows a "gift or gratuity" to the state upon condition that the state consents to suit in federal court. A state's voluntary acceptance of a gift or gratuity by the federal government, which is expressly conditioned on

the state waiving its immunity, is an "unequivocal" expression of the states intent to waive its sovereign immunity. See *MCI*, 222 F.3d at 341; *Accord MCI Telecommunications Corp. v. Public Service Commission*, 216 F.3d 929 (10th Cir. 2000). See also, *Garrett v. Alabama Department of Youth Services*, 2003 U.S. App. LEXIS 18851; 14 Am. Disabilities Cas. (BNA) 1386, (11th Cir. 2003), holding that state agencies waive Eleventh Amendment immunity by accepting Federal funds. However, contrary to this Court's decision in *College Savings*, and that of the 7th, 10th and 11th circuits, the Federal Circuit now inexplicably appears to hold that *College Savings* dismissed entirely the concept of constructive waiver. See, *Xechem International v. The University of Texas et al.*, 382 F.3d 1324, 1331 (Fed. Cir. 2004).

In *College Savings*, the Supreme Court recognized a fundamental difference between a state merely engaging in a federally regulated or ordinary business activity as opposed to voluntarily accepting a federal gratuity. See *College Savings*, 527 U.S. at 686-87, 119 S. Ct. 2219 (citing *Petty v. Tennessee-Missouri Bridge Commission*, 359 U.S. 275, 79 S. Ct 785, 3 L. Ed. 2d 804 (1959) (state's waiver as a condition for Congressional approval of an interstate compact is a valid waiver as Congressional approval of a compact is a gratuity); *South Dakota v. Dole*, 483 U.S. 203, 107 S.Ct. 2793, 97 L. Ed. 2d 171 (1987) (Congress may impose conditions on a state's acceptance of federal funds as the federal funds were a "gift" that Congress was not obligated to give). Common to both *Dole* and *Petty* was that "Congress had the prerogative to bestow a gratuity and that by accepting the gratuity, the states agreed to undertake certain actions that...could not have otherwise have taken." *MCI*, 222 F.3d at 341. Conversely, in *Florida Prepaid*, the state was merely conducting ordinary business activities when it was sued for patent infringement. *Florida Prepaid* 527 U.S. at 631, 119 S. Ct. at 2203. Florida had not accepted a gift or

gratuity from Congress, and therefore Congress had no authority to impose any conditions on the state. *New Star Laser, Inc. v. Regents of the University of California*, 63 F. Supp. 2d 1240, 1243 (E.D. Cal. 1999) (citing *Florida Prepaid* at 644-647, 119 S. Ct. at 2210-11). The "validity of a purported waiver turns on whether the waiver is conditioned on the state's truly voluntary acceptance of a federal gratuity." *Id.* Unsurprisingly, the Fifth Circuit has also held that a state constructively waives its Eleventh Amendment immunity by non-verbal conduct when it accepts a gift or gratuity from Congress after being given clear and unambiguous statutory notice that the gift or gratuity was conditioned on waiver of immunity. *AT&T Communications v. Bellsouth Telecommunication, Inc.* No. 99-30421 (5th Cir. January 16, 2001). *See also, Bell Atlantic Maryland v. MCI Worldcom*, 2001 VI. 123663 (4th Cir. February 14, 2001).

A state's acquiring and owning a patent is substantially different from conducting ordinary business activities, as the Federal Circuit has incorrectly asserted. See for example, *New Star Lasers*, 63 F. Supp. at 1243. At stake is the validity of a patent, which "constitutes a unique form of nationally recognized intellectual property, created by Congress pursuant to its authority under the Patent Clause." *Id.* (citing U.S. Const. Art. I, Sec. 8). A patent can only be obtained through the federal Patent and Trademark Office where the patent owner receives an "ironclad monopoly for a limited number of years" in exchange for disclosure of the art. *Id.* (citations omitted). The would-be patentee must also agree to disclose the true inventors, among other things. 35 U.S.C. § 1 et seq. Thus, acquiring a patent is more than "ordinary commercial activity" - it is a "gift or gratuity" bestowed by the federal government. *Id.* Furthermore, by acquiring a federal patent:

> [t]he owner receives the benefit of a nationally recognized right governed by nationally uniform laws, and enforceable, indeed solely enforceable, in a national system of courts. 28 U.S.C. § 1338; Federal Courts Improvement Act of 1982, PubL. 97-164, 96 State. 25 (April 2, 1982) (crating Court of Appeals for the Federal Circuit). Without the judicial enforcement provided by the national government, a patent would have little or no value; without a patent, the possessor of the technology would be forced to conceal the art in reliance on varying trade secret laws of the several States (emphasis added).

Id. at 1244

Thus, in *New Star Laser*, the Regents constructively waived their Eleventh Amendment immunity by accepting a gift similarly to the states in *Petty* and *Dole*. Id. 1244-45. *Accord, McGuire v. Regent of the University of Michigan et al.*, 2000 WL 1459435, *4 (S.D. Ohio, 2000) (where the court held that a federally registered trademark is a federal gift or gratuity or "federal beneficence" "for which the state's waiver of immunity can be compelled").

As in the action before this Court, at issue in *New Star Lasers* was a declaration of non-infringement of a patent. A "declaration of non-infringement has become a significant component of the patent system". *Id.* Patents are subject only to a limited level of review and testing prior to issuance, resulting in invalid patents being issued. *See Id.* Consequently, a patent holder with an invalid patent could threaten others with infringement but never take legal action. The party challenged with infringement would have no legal recourse to invalidate the patent, yet could be

prevented from moving forward due to the underlying threat of heavy penalties for infringement. The current patent holder could continue to enjoy the benefits of a potentially invalid patent merely by threatening others with patent infringement. *Id.* Therefore, a suit for declaration of non-infringement is "an integral part of the patent scheme" that provides the *quid pro quo* or legal mechanism to challenge the validity of a patent. *Id.*

The case at hand is virtually identical to the facts presented in *New Star Lasers.* Respondents accepted a gift or gratuity from the federal government when it applied for and received a patent. By accepting the '205 and '333 patents, Respondents unequivocally and voluntarily waived its Eleventh Amendment immunity with respect to patent enforcement and inventorship corrective actions. The State of Texas through Respondents simply cannot acquire a federal patent, take full advantage of all the benefits of a federal property right, and then conveniently reject its limitations. *New Star Lasers,* 63 F. Supp. 2d at 1244.

Further on this point, it is clear that a state waives its Eleventh Amendment immunity when it consents to federal court jurisdiction by voluntarily appearing in federal court. *The Regents of the University of New Mexico v. Knight,* 321 F.3d 1111, 1124 (Fed. Cir. 2003), citing *Clark v. Barnard,* 108 U.S. 436, 447, 27 L. Ed. 780, 2 S. Ct. 878 (1883) and *Gunter v. Atl. Coast Line R.R.,* 200 U.S. 273, 284, 50 L. Ed. 477, 26 S. Ct. 252 (1906) ("Where a State voluntarily becomes a party to a cause and submits its rights for judicial determination, it will be bound thereby and cannot escape the result of its own voluntary act by invoking the prohibitions of the Eleventh Amendment"). *See also, Lapides v. Board of Regents of the University System of Georgia, et al.,* 535 U.S. 613; 122 S. Ct. 1640; 152 L. Ed. 806 (2002), wherein a state attempted to assert its Eleventh Amendment immunity for the very claim that it brought into federal court, the Court held that when a

state voluntarily invokes the jurisdiction of the federal court and consents to removal to federal court, Eleventh Amendment immunity is waived. *Id.* In *Lapides*, this Court further reasoned,

> [A]n interpretation of the Eleventh Amendment that finds waiver in the litigation context rests upon the Amendment's presumed recognition of the judicial need to avoid inconsistency, anomaly, and unfairness, and not upon a State's actual preference or desire, which might, after all, favor selective use of immunity to achieve litigation advantages.

Id at 620.

This Court also stated,

> It would seem anomalous or inconsistent for a State both (1) to invoke federal jurisdiction, thereby contending that the 'Judicial power of the United States' extends to the case at hand, and (2) to claim Eleventh Amendment immunity, thereby denying that the 'Judicial power of the United States' extends to the case at hand. And a Constitution that permitted states to follow their litigation interests by freely asserting both claims in the same case could generate seriously unfair results.

Id. Lapides, 535 U. S. at 619.

Following the *Lapides* Court, the Federal Circuit in the *Regents of the University of New Mexico*, 321 F.3d at 1125 held that,

> '[S]eriously unfair' results could obtain if a state were permitted to file suit in federal court seeking to enforce a right to ownership of patents arising from certain contractual agreements and conduct and, at the same time, to claim immunity from liability for royalties or other compensation arising from those same contracts and conduct.

In the present case, Respondents voluntarily invoked the jurisdiction of the United States Patent and Trademark Office ("PTO") in applying for and obtaining the '205 and '333 patents, and by Respondents seeking to secure and enforce their alleged rights to exclusive inventorship and ownership of these patents by claiming sole inventorship as to their employee and agent Dr. Andersson. The PTO is a federal quasi-judicial entity performing quasi-judicial functions through quasi-judicial officials. *Western Electric Company, Incorporated v. Piezo Technology, Inc.*, 860 F.2d 428, 431 (Fed. Cir. 1988) citing *Butterworth v. United States ex rel. Hoe*, 112 U.S. 50, 67, 5 S. Ct. 25, 28 L. Ed. 656 (1884) ("that it was intended that the Commissioner of Patents, in issuing or withholding patents...should exercise quasi-judicial functions, is apparent from the nature of the examinations and decision he is required to make"), *United States v. American Bell Tel. Co.*, 128 U.S. 315, 363, 9 S. Ct. 90, 32 L. Ed. 450 (1888) ("the patent...is the result of a course of proceeding, quasi-judicial in its character"); and *Chamberlin v. Isen*, 779 F.2d 522, 524 (9th Cir. 1985) ("It has long been recognized that PTO employees perform a 'quasi-judicial' function in examining patent applications").

Respondents, having purposely invoked the jurisdiction of the quasi-judicial federal agency of the PTO in applying for and receiving the '205 and '333 patents and affirmatively asserting sole inventorship of Dr. Andersson and ownership of these patents to successfully persuade the PTO to issue patents to Respondents, now seek to hide behind Eleventh Amendment immunity in an attempt to hide from the PTO and the Courts the true inventors and owners of these patents. Respondents through their claim of Eleventh Amendment immunity seek to block a determination of correct inventorship in a District Court under a provision of United States patent law which it expressly consented to in applying for patents. This action is not only "seriously unfair", but incorrect as Respondents have expressly and unequivocally waived Eleventh Amendment immunity by submitting to the jurisdiction of the PTO. *See Lapides,* supra. Contrary to the Federal Circuit's position, it is both inconsistent and seriously unfair to allow Respondents to voluntarily avail itself of the quasi-judicial Patent Office in filing for and obtaining patents, affirming exclusive patent inventorship to the Patent Office, and to simultaneously claim immunity under the Eleventh Amendment to a challenge of true inventorship. Such action is nothing more than a disfavored abuse of the judicial system by "selective use of immunity" to achieve litigation advantages. *Lapides,* supra.

Accordingly, a Federal District Court has jurisdiction to hear inventorship claims under 35 U.S.C. § 256 with respect to patents allegedly owned by University of Texas M.D. Anderson Cancer Center, and the Board of Regents or the University of Texas System.

C. The due process rights of Petitioner to a fair hearing as to its inventorship and ownership rights in United States patents in suit constitute a fundamental constitutional right which has been deprived by Respondents' Eleventh Amendent Immunity

Petitioner has conceived and developed valuable property rights which are now embodied in the claimed subject matter of the patents in suit. Owing to the District and Federal Circuit court's decisions, petitioner has been completely deprived of its valuable property rights without due process of law by the incorrect application of Eleventh Amendment immunity. Contrary to the Federal Circuit's decision, Petitioner may not bring suit in state court against Respondents in an action for inventorship correction, as this Court has held that sovereign immunity bars suits in state courts just as it does in federal courts. *South Carolina State Ports Authority v. Federal Maritime Commission*, 243 F.3d 165, 169 (4th Cir. 2001), affirmed, *FMC v. South Carolina State Ports Authority*, 534 U.S. 743, 152 L. Ed. 2d 962, 122 S. Ct. 1864 (2002), citing *Alden v. Maine*, 527 U.S. 706, 711, 144 L. Ed. 2d 636, 119 S. Ct. 2240 (1999).

Even if Respondents, the State of Texas, could be sued in state court, as inexplicitly suggested in the Federal Circuit's decision, there would exist no subject matter jurisdiction for patent inventorship correction actions, as such suits may only be brought in Federal District Courts. *MCV, Inc. v. King-Seeley Thermos Co.*, 870 F.2d 1568, 1570 (Fed. Cir. 1989) ("Is a suit in district court for determination of co-inventorship and correction of a patent under 35 U.S.C. § 256 permissible, and is it an action 'arising' under the patent laws for purposes of 28 U.S.C. § 1338(a) so that we have jurisdiction under 28 U.S.C. § 1295(a)(1)? The answer is yes."

Further, Respondents the University of Texas et al. may be co-inventors, and thus co-owners, of the patents in suit, as explicitly provided by the U.S. patent laws. 35 U.S.C. § 116. Joint owners of a patent do not have to account to other owners, however. 35 U.S.C. § 262. Thus, a "taking action" would not be proper in this case, as, at most, Respondents are merely co-inventors and co-owners of an undivided portion of patents. Petitioner should be afforded its due process rights under the U.S. Constitution to perfect corrected inventorship and ownership rights to its' undivided, and unaccountable, property interests in the patents in suit. This is not a patent infringement action, as repeatedly referenced by the Federal Circuit's decision; Petitioner's action is one for patent inventorship and ownership correction, and for deprivation of Petitioner's constitutional rights. As correctly noted by the Federal Circuit, "a patent for an invention is as much property as a patent for land". *Consolidated Fruit Jar Co. v. Wright*, 94 U.S. (4 Otto) 92, 96 (1876). The deprivation of Petitioner's valuable property interests in the patents in suit by the improper application of Eleventh Amendment immunity is an unconstitutional deprivation of Petitioner's interests without due process at law. *Florida Prepaid*, 527 U.S. at 642-43.

1. *Ex parte Young* is not applicable to an action for change of inventorship in a granted U.S. patent where non-named inventors without deceptive intent seek to secure their inventorship and ownership rights to a valid and enforceable patent grant.

The Federal Circuit has wrongly implied that *Ex Parte Young* may be applicable to the present case. See, *Ex parte Young*, 209 U.S. 123, 52 L. Ed. 714, 28 S. Ct. 441 (1908). This well recognized exception to Eleventh Amendment immunity "allows federal courts, 'notwithstanding the absence of consent', waiver or evidence of Congressional assertion of national hegemony, (to) enjoin state officials to conform future conduct to the requirements of federal law." *Rosie D. v. Swift*, 310 F.3d 230, 234 (1st Cir. 2002).

It is submitted to this Court that Petitioner should not be forced to now potentially irreversibly destroy their own property rights in the patents in suit by application of *Ex Parte Young*, in proving that Respondents', through their employee/agent, have intentionally misrepresented inventorshp to the Patent Office, or otherwise from acting in violation of federal law. Such will only serve to render unenforceable and worthless Petitioner's valuable property. See, *Frank's Casing Crew & Rental Tools, Inc. v. Vincent*, supra. Thus, *Ex parte Young* is not applicable to an action for change of inventorship in a granted U.S. patent where non-named inventors without deceptive intent seek to secure their inventorship and ownership rights to a valid and enforceable patent grant.

XII. CONCLUSION

For all of the forgoing reasons, Petitioner Xechem respectfully submits that this Court should grant the petition in that the decision of the Court of Appeals for he Federal Circuit directly conflicts with decisions of this Court, and of several other Circuits. Furthermore, this Court should grant the petition to resolve circuit conflicts regarding constructive waiver of Eleventh Amendment immunity, and to also resolve questions of whether a state may argue for and be granted a U.S. patent after purportedly complying with U.S. patent law and regulations, and on the other hand deny Federal District Court scrutiny of it's compliance while claiming Eleventh Amendment immunity.

Respectfully submitted,

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APPENDIX

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United States Court of Appeals for the Federal Circuit

03-1406

XECHEM INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER and BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,

Defendants-Appellees.

John P. Luther, Law Office of John P. Luther, of Kent, Washington, argued for plaintiff-appellant.

David L. Parker, Fulbright & Jaworski L.L.P., of Austin, Texas, argued for defendants-appellees. With him on the brief were Marcy Hogan Greer and Robert E. Hanson, Jr..

Appealed from: United States District Court for the Southern District of Texas

Judge Ewing Werlein, Jr.

United States Court of Appeals for the Federal Circuit

03-1406

XECHEM INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER and BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,

Defendants-Appellees.

DECIDED: August 31, 2004

[Entered August 31, 2004]

Before NEWMAN, GAJARSA, and LINN, Circuit Judges.

Opinion for the court filed by Circuit Judge NEWMAN; additional views by Judge Newman.

NEWMAN, Circuit Judge.

Xechem International, Inc., a biopharmaceutical company, brought suit against the University of Texas M.D. Anderson Cancer Center and the Board of Regents of the University of Texas System (collectively "the University") in the United States District Court, raising several federal and state counts arising from a collaborative project between

Xechem and the University. In response to the complaint the University asserted its Eleventh Amendment and state immunity from suit, and the United States District Court for the Southern District of Texas granted the University's motion to dismiss on the pleadings, Fed. R. Civ. P. 12(b)(6).[1] The only issue on appeal is whether the University is subject to suit in federal court to obtain correction of the inventorship of United States Patents No. 5,877,205 and 6,107,333, the patents flowing from the project.

We affirm the dismissal, for Supreme Court precedent controls the arguments raised by Xechem with respect to waiver or abrogation of the University's Eleventh Amendment immunity.

Standards of Review

The University's motion to dismiss was brought under Fed. R. Civ. P. 12(b)(6) (dismissal for failure to state a claim upon which relief can be granted). When dismissal is on the pleadings, the plaintiff's well-pleaded factual allegations are accepted as true and all reasonable factual inferences are drawn in its favor. See Albright v. Oliver, 510 U.S. 266, 268 (1994) (on motion to dismiss on the pleadings, disputed material facts are viewed in the light most favorable to the complainant).

Dismissal under Rule 12(b)(6) receives plenary appellate review. Boyle v. United States, 200 F.3d 1369, 1371 (Fed. Cir. 2000); Young v. AGB Corp., 152 F.3d 1377, 1379 (Fed. Cir. 1998). Matters of constitutional law and interpretation also receive plenary review. Arbon Steel & Serv. Co. v. United States, 315 F.3d 1332, 1334 (Fed. Cir.

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1 Xechem Int'l, Inc. v. University of Texas M.D. Anderson Cancer Ctr., No. H-02-1013 (S.D. Tex. March 19, 2003).

2003); Florida Sugar Mktg. & Terminal Assoc., Inc. v. United States, 220 F.3d 1331, 1333 (Fed. Cir. 2000).

BACKGROUND

The basic facts are generally undisputed: Xechem and the University in 1995 entered into a Sponsored Laboratory Study Agreement, with financial and technical support by Xechem, for the purpose of developing a pharmaceutical formulation that would enhance the solubility and thereby the effectiveness of the cancer drug paclitaxel. The persons principally involved in the project were Dr. Ramesh C. Pandey, president and CEO of Xechem; Dr. Luben K. Yankov, a scientist employed by Xechem; and Dr. Borje S. Andersson and Dr. Elias Anaissie, scientists employed by the University.

The complaint states that a successful formulation was developed, and that Xechem prepared a patent application naming Dr. Pandey of Xechem and Dr. Andersson of the University as joint inventors, and in early 1996 sent the draft application to the University. The University objected to the designation of inventorship, and on June 28, 1996 the University filed a patent application in the United States Patent and Trademark Office, naming Dr. Andersson as sole inventor. On November 13, 1996 Dr. Pandey wrote to the University as follows:

> Further to our conversation of today, as you have requested I am now forwarding you this letter in which I recognize Dr. Borge S. Andersson, as the sole inventor of the above referenced patent application.
>
> I look forward to receiving Dr. Andersson's comments of the Draft Patent Application and to wrap-up the licensing

negotiations concerning the subject matter of the application.

On August 18, 1997 Xechem and the University entered into a Patent and Technology License Agreement whereby Xechem received the exclusive worldwide license to manufacture and market these paclitaxel formulations, and Xechem agreed to pay certain continuing sums and a royalty. Xechem also agreed to pay the costs of obtaining the patents in the United States and foreign countries. The University's patent application issued as the '205 patent on March 2, 1999, and a divisional application, also naming Dr. Andersson as sole inventor, issued as the '333 patent on August 22, 2000. Both patents were assigned by Dr. Andersson to the University.

On February 15, 2000 Xechem was notified that the University considered the License Agreement to have terminated automatically no later then December 31, 1998, due to Xechem's alleged insolvency, and that any use of this technology by Xechem was deemed to be patent infringement. Xechem then filed suit in federal court, presenting several counts sounding in tort and contract and also seeking correction of inventorship and a declaration of non-infringement. Xechem stated that Dr. Pandey made a mistake when he acquiesced in the naming of Dr. Andersson as sole inventor, and asked the court to determine the correct inventorship. Apparently upon the University's claim of sovereign immunity from state as well as federal action, the state law tort and contract counts were withdrawn by Xechem. This appeal relates only to the dismissal, on Eleventh Amendment grounds, of the inventorship correction claim.

DISCUSSION

The University of Texas is deemed to be an arm of the State of Texas, see Tex. Code §441.101(3), and Xechem does not dispute that the University is properly accorded Eleventh Amendment immunity.[1] See Regents of the Univ. of New Mexico v. Knight, 321 F.3d 1111, 1124 (Fed. Cir. 2003) (recognizing the status of a state university as an arm of the state).

The Supreme Court has addressed Eleventh Amendment immunity as it pertains to violation of federal patent and trademark laws. In Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627 (1999) and College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board, 527 U.S. 666 (1999) the Court invalidated the legislative abrogation of state immunity from suit under these laws. In Florida Prepaid the Court ruled that the Eleventh Amendment was violated by the Patent and Plant Variety Protection Remedy Clarification Act of 1992, Pub. L. 102-560, 106 Stat. 4230 (codified at 35 U.S.C. §§271(j), 296). In College Savings the Court reached the same result with respect to abrogation of immunity by the Trademark Remedy Clarification Act of 1992, Pub. L. 102-542, 106 Stat. 3567 (codified at 15 U.S.C. §§ 1051, 1114, 1122). The Court held that Eleventh Amendment immunity may be abrogated "only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result," thereby invoking the Fourteenth Amendment. Florida Prepaid, 527 U.S. at 643. The Court also referred to lack of a "pattern of patent

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[1] Amendment XI. The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

infringement by the States," id. at 640, in suggesting that legislative remedy had not been shown to be necessary.

The Court stressed the exclusive role of the Fourteenth Amendment[1] in abrogation of Eleventh Amendment immunity in Tennessee v. Lane, ___ U.S. ___, 124 S. Ct. 1978 (2004), where the Court sustained abrogating legislation against constitutional challenge, holding that "Title II [of the Americans with Disabilities Act] unquestionably is valid §5 legislation as it applies to the class of cases implicating the accessibility of judicial services." 124 S. Ct. at 1993. The Court stated:

> Title II -- unlike RFRA [the Religious Freedom Restoration Act of 1993, held unconstitutional in City of Boerne v. Flores, 521 U.S. 507 (1997)], the Patent Remedy Act [held unconstitutional in Florida Prepaid, 527 U.S. at 547-48], and the other statutes we have reviewed for validity under §5 -- reaches a wide array of official conduct in an effort to enforce an equally wide array of constitutional guarantees.

124 S. Ct. at 1992. Although sustaining the authority of Congress under the Fourteenth Amendment to abrogate the states' immunity, the Court made clear that the issues resolved in Florida Prepaid were not being reopened. In Tennessee v. Lane the Court explained that Florida Prepaid had "further defined the contours of Boerne's 'congruence

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[1] Amendment XIV. Section 1. . . . nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

Section 5. The Congress shall have power to enforce, by appropriate legislation, the provisions of this article.

and proportionality' test," 124 S. Ct. at 1987, and reiterated that suits against states for patent infringement had not been shown to raise Fourteenth Amendment issues.

Xechem argues that the Eleventh Amendment does not bar an action to correct inventorship under 35 U.S.C. §256, because the correction of inventorship will change the ownership of the patents, thereby raising property issues cognizable under the due process clause of the Fourteenth Amendment. Xechem also argues that correction of inventorship does not require participation or consent of the owner of the patent, and thus can proceed in federal court despite the University's objection. Xechem further argues that because the University's employee Dr. Andersson applied for and was granted these patents by the United States Patent and Trademark Office, a federal agency, the University consented to federal jurisdiction, at least for correction of the identity of the applicant. Xechem also argues that patents are a gift or gratuity granted by the federal government, and that the University's acceptance of the patents is a waiver of Eleventh Amendment immunity. The University responds that Supreme Court precedent has disposed of all of these theories, and that the complaint was properly dismissed for failure to state a claim upon which relief can be granted.

A

Xechem argues that the University waived its Eleventh Amendment immunity when it entered into this collaborative research agreement, and further waived its immunity by contracting with Xechem in the License Agreement for purposes of commercial gain. Xechem argues that by entering into these contractual and commercial arrangements the University waived objection to federal court jurisdiction to secure constitutionally protected property rights, and for issues that can be decided only in federal court under preemptive federal statutes.

The University responds that it did not waive its immunity by entering into these arrangements, for any waiver must be express and clear and "altogether voluntary," and cannot be inferred. In College Savings the Court explained that waiver of the Eleventh Amendment right to be immune from the authority of federal courts can occur in only two circumstances: first, if the state on its own initiative invokes the jurisdiction of the federal courts; and second, upon a clear declaration by the state of its intent to submit to federal jurisdiction. 527 U.S. at 675-76. Responding to the argument that sovereign immunity should be deemed waived when a state enters into commercial activity, the Court pointed out that the Eleventh Amendment does not make that distinction, id. at 686, and that such a distinction is inapplicable because "the constitutional role of the States sets them apart from other employers and defendants." Id. at 685-86 (quoting Welch v. Texas Dep't of Highways & Public Transp., 483 U.S. 468, 477 (1987)).

Xechem argues that patent law finds its authority in the Constitution, and that no state court can adequately ensure that the federal interest in promoting progress of the useful arts is upheld. Xechem also argues that this case calls for an interpretation of federal law by federal courts, because inventorship is a matter of exclusive federal jurisdiction. However, the Court has dealt definitively with the argument that a state waives its immunity by entering into arrangements controlled by federal law and reviewable only in federal court. In College Savings the Court reaffirmed the principles of Seminole Tribe of Florida v. Florida, 517 U.S. 44 (1996) and Fitzpatrick v. Bitzer, 427 U.S. 445 (1976), and overruled Parden v. Terminal Railway of the Alabama State Docks Department, 377 U.S. 184 (1964).

In Seminole Tribe the Court discussed the congressional power to abrogate state immunity by federal statute, and reaffirmed that the Commerce Clause is not a source of such power. In Parden the Court had relied on the Commerce Clause to hold that when a state voluntarily enters into federally regulated activity -- in Parden, operating a railroad -- the state is deemed to have consented to federal jurisdiction arising from that activity, in that case an action under the Federal Employers' Liability Act. In overruling Parden's constructive waiver, the Court stressed in College Savings that a state's waiver of Eleventh Amendment rights cannot be imposed or implied based on a state's entry into commerce, but must be founded on a "clear declaration" by the state of its intent to submit to federal jurisdiction. Id. at 675 (quoting Great Northern Life Ins. Co. v. Read, 322 U.S. 47, 54 (1944)). Such a declaration was not made by the University in entering into its various relationships and contracts with Xechem.

B

Xechem also argues that the University constructively consented to federal jurisdiction by causing its employee Dr. Andersson to apply for United States patents. Xechem argues that the University made a clear and voluntary waiver of immunity when it entered the Patent and Trademark Office and sought its legal benefits, and that the University cannot both obtain patents and "hide behind the Constitution." Xechem states that by filing patent applications with a federal agency, accompanied by Dr. Andersson's averral that he is the original and sole inventor, the University consented to correction of such erroneous averral in the only court that, according to Xechem, can order such correction. See 35 U.S.C. §256 ¶2:

> §256. Whenever through error a person is named in an issued patent as the inventor, or

> through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.
>
> The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section. The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

The University states that this statute does not waive state immunity, either expressly or by implication. In College Savings the Court negated the argument that a state's voluntary participation in activities controlled by federal statute imposes a consent to suit arising from those activities. The Court stated that "we think where the constitutionally guaranteed protection of the States' sovereign immunity is involved the point of coercion is automatically passed -- and the voluntariness of waiver destroyed -- when what is attached to the refusal to waive is the exclusion of the State from otherwise lawful activity." 527 U.S. at 689 (overruling Parden).

Xechem also argues that a state's invocation of the authority of the PTO to grant patents is analogous to the state's invocation of federal authority to enforce its patent rights at state initiative, the latter clearly serving to waive Eleventh Amendment immunity. See Regents of the University of New Mexico, 321 F.3d at 1125 (recognizing the

"inconsistency and unfairness that could result from allowing a state that voluntarily avails itself of the federal courts to simultaneously claim immunity under the Eleventh Amendment") (citing Lapides v. Board of Regents of the Univ. Sys. of Georgia, 535 U.S. 613 (2002)). Such analogy does not withstand scrutiny, for waiver must be clear, explicit, and voluntary, and cannot be imposed on a state that has not voluntarily entered federal jurisdiction.

Thus the argument must be rejected that a state's entry into the patent system is a constructive waiver of immunity for actions in federal court against the state under the patent law.

C

Xechem also argues that the grant of a patent is a "gift or gratuity" by the government, whereby acceptance of the grant is a constructive waiver of immunity, citing Petty v. Tennessee-Missouri Bridge Commission, 359 U.S. 275 (1959) and South Dakota v. Dole, 483 U.S. 203 (1987). The Court confirmed in Petty and again in Dole that Congress can condition receipt of federal funds on a commensurate waiver of state immunity. However, in College Savings the Court explained that such conditions on federal disbursements are "simply not analogous to Parden-style conditions attached to a State's decision to engage in otherwise lawful commercial activity." 527 U.S. at 678.

The grant of a patent is not a disbursement of governmental largesse. A gift is "nothing more than the transfer of property without consideration." Kehr v. Smith, 87 U.S. 31, 34 (1873). In contrast, the government grant of a property right, viz. the right to exclude for a limited time, is conditioned on the creation and public disclosure of a new and useful invention. See Pfaff v. Wells Electronics, Inc., 525 U.S. 55, 63 (1998) ("the patent system represents a carefully

crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time").

Patent activity is commercial activity, not governmental beneficence. The holdings of Seminole Tribe, and the overruling of Parden, have foreclosed the broad ruling that by obtaining patents the state constructively waived its Eleventh Amendment immunity as to any federal proceeding involving those patents. Xechem argues, as it did in the district court, that the reasoning in New Star Laser, Inc. v. Regents of the University of California, 63 F. Supp.2d 1240 (E.D. Cal. 1999) supports a theory of constructive waiver. The New Star Laser court stated that although the Patent Remedy Act of 1992 may have failed as abrogating legislation, it succeeded as constructive waiver legislation. The Court explicitly rejected this distinction in College Savings, stating that "constructive waiver is little more than abrogation under another name." 527 U.S. at 684.

D

Xechem also argues that the University is not a necessary party to this action to correct inventorship, and therefore that it need not consent to or participate in the hearing, provided only that it received notice of the hearing. Under 35 U.S.C. §256 ¶2 a court may order correction of inventorship over the objection of those adversely affected. See Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1553 (Fed. Cir. 1997). Xechem argues that since the University cannot prevent the §256 action from proceeding, both consent and immunity are irrelevant. Thus Xechem argues that the Eleventh Amendment does not bar suit to correct inventorship of a patent that is assigned to the University. The district court did not discuss whether the assignee is a necessary party to a §256 ¶2 suit to correct inventorship.

However, state entities are the only party-defendants to this suit; with no defendant, there is no suit.

The pleadings stated that inventorship can be corrected only in federal court, but ownership issues are generally the province of state courts. Although the Federal Circuit has held that inventorship is determined under federal law, see MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568, 1570 (Fed. Cir. 1989), state courts can apply federal law to issues properly before the state court. See Speedco, Inc. v. Estes, 853 F.2d 909, 914 (Fed. Cir. 1988) (citing Brady v. Southern Ry. Co., 320 U.S. 476, 479 (1943)). Federal preemption of causes arising under the Patent Act does not include matters of ownership or license. In Jim Arnold Corp. v. Hydrotech Sys., Inc., 109 F.3d 1567, 1577 (Fed. Cir. 1997) this court held that although an assignment and royalty agreement concerned patent property, that did not remove from the state courts the various disputes concerning property rights. Similarly, in Prize Frize, Inc. v. Matrix (U.S.), Inc., 167 F.3d 1261 (9th Cir. 1999) the Ninth Circuit held that an alleged deprivation of patent ownership through various unlawful or unfair actions was not a claim under federal law; the court cited Jim Arnold for the holding that "[c]laims concerning patent ownership do not create federal jurisdiction." 167 F.3d at 1264.

Although the Court recognized in Florida Prepaid that possible state court remedies may be "uncertain" or "less convenient" or "might undermine the uniformity of patent law," the Court held that uncertainty and other disadvantages flowing from a state's claim of Eleventh Amendment immunity did not deprive a patentee of property without due process of law. 527 U.S. at 644-45. The Court stated that it was necessary to show that the state action "left [the patentee] without a remedy under state law," id. at 647, before the due process concerns of the

Fourteenth Amendment could be implicated. Such a showing has not been made.

Conclusion

Xechem's pleadings and representations do not meet the requirements of precedent for waiver or abrogation of a state's Eleventh Amendment immunity. Thus the district court's dismissal under Rule 12(b)(6) is

AFFIRMED.

United States Court of Appeals for the Federal Circuit

03-1406

XECHEM INTERNATIONAL, INC.,

Plaintiff-Appellant,

v.

THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER and BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,

Defendants-Appellees.

NEWMAN, Circuit Judge, additional views.

I write separately to state my concern lest the caveats and safeguards recognized by the Supreme Court in its rulings in Florida Prepaid and College Savings[1] become submerged in generalizations of absolute state immunity. The Court observed in Florida Prepaid that if no state court remedy were available for patent infringement, such failure of recourse could raise the due process concerns of the Fourteenth Amendment. Compare Tennessee v. Lane, 124 S. Ct. 1978 (2004) (legislative abrogation sustained on due process grounds for violation of Title II of the Americans with Disabilities Act of 1990) with Board of Trustees of

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[1] In Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 527 U.S. 627 (1999) and College Savings Bank v. Florida Prepaid Postsecondary Education Expense Board, 527 U.S. 666 (1999) the Court invalidated the 1992 legislative abrogation of state immunity from suit under the patent and trademark laws.

Univ. of Ala. v. Garrett, 531 U.S. 356 (2001) (legislative abrogation rejected in claims for money damages for violation of Title I of the ADA). Although Xechem is here seeking judicial, not legislative, relief, its due process claims on the ground that there is no alternative remedy have not been fully explored. Nor did Xechem in this action seek the alternative path marked by Ex parte Young, 209 U.S. 123 (1908). These aspects are not raised in this dismissal on the pleadings.

Intellectual Property and the Fourteenth Amendment

In Florida Prepaid the Court, discussing abrogation of Eleventh Amendment immunity, stated that "only where the State provides no remedy, or only inadequate remedies, to injured patent owners for its infringement of their patent could a deprivation of property without due process result." 527 U.S. at 643, quoting Hudson v. Palmer, 468 U.S. 517, 539 (1984) (O'Connor, J., concurring) that "in challenging a property deprivation, the claimant must either avail himself of the remedies guaranteed by state law or prove that the available remedies are inadequate," in turn citing Parratt v. Taylor, 451 U.S. 527, 537-544 (1981). Throughout the evolution of Eleventh Amendment jurisprudence the Court has stressed the rigor of the restraint imposed by the Fourteenth Amendment on the federal government as well as on the states. Thus the Court found in Florida Prepaid that patent infringement by states did not appear to be a sufficiently prevalent national problem to warrant §5 abrogation. And in College Savings the Court held that unfair competition by a state based on false advertising did not raise a Fourteenth Amendment property issue; the Court observed that general business interests are not property rights, and held that while trademarks are constitutionally protected property, false advertising has no relation to the right to exclude and does not raise a constitutional issue. The Court recognized, however, that

"the assets of a business . . . unquestionably are property, and any state taking of these assets is unquestionably a 'deprivation' under the Fourteenth Amendment." College Savings, 527 U.S. at 675.

Xechem has asserted that in this case inventorship controls ownership and the right to practice the patented invention -- fundamentals of patent property. See Consolidated Fruit-Jar Co. v. Wright, 94 U.S. (4 Otto) 92, 96 (1876) ("A patent for an invention is as much property as a patent for land"). Xechem's claim on its face raises issues of property and due process. The Court explained in Florida Prepaid that "[i]n procedural due process claims, the deprivation by state action of a constitutionally protected interest . . . is not in itself unconstitutional; what is unconstitutional is the deprivation of such an interest without due process of law." 527 U.S. at 642-43 (quoting Zinermon v. Burch, 494 U.S. 113, 125 (1990)). However, the Court in Florida Prepaid required a showing -- more than an allegation -- of the unavailability of adequate remedy in state court. Although Xechem argues that only federal courts can order a change of inventorship, precedent has not dealt with whether state courts are precluded from resolving issues of ownership of patent property when ownership is based on inventorship.

In Florida Prepaid the Court noted that patent infringement by the state might be remedied in state court on the traditional state law grounds of taking of property or conversion, 527 U.S. at 644 n.9, observing that a factor in the due process provision of the Fourteenth Amendment is whether any remedy is otherwise available. However, precedent establishes no ready rule as to when the nature of the wrong and remedy warrant recourse to the Fourteenth Amendment. On the record before us, and the premises of Rule 12(b)(6), the question of alternative remedy was not explored. We are told that various state law counts were

withdrawn from the complaint in the district court; however, the potential presence of other issues does not avoid this dismissal on the pleadings. These questions are not resolved by today's decision.

The Doctrine of Ex Parte Young

The Court in Florida Prepaid also mentioned potential recourse to the doctrine of Ex parte Young, 209 U.S. 123 (1908), which held that a state employee is not shielded by Eleventh Amendment immunity if the employee has acted in violation of federal law. The Court held that although state immunity barred suit in federal court against Mr. Young in his capacity as attorney general of Minnesota, he could be sued in his personal capacity and his wrongful actions enjoined. While cautioning that "the real interests served by the Eleventh Amendment are not to be sacrificed to elementary mechanics of captions and pleading," Idaho v. Coeur d'Alene Tribe of Idaho, 521 U.S. 261 (1997), the Court explained the two general situations in which Ex parte Young has been applied:

> Putting aside the acts of state officials which are plainly ultra vires under state law itself, there are, in general, two instances where Young has been applied. The first is where there is no state forum available to vindicate federal interests, thereby placing upon Article III courts the special obligation to ensure the supremacy of federal statutory and constitutional law.

Coeur d'Alene, 521 U.S. at 270 (citations omitted).

> Even if there is a prompt and effective remedy in a state forum, a second instance in which Young may serve an important

> interest is when the case calls for the interpretation of federal law. This reasoning, which is described as the interest in having federal rights vindicated in federal courts, can lead to expansive application of the Young exception.

Id. at 274 (citations omitted). The Court again reviewed the application of Ex parte Young against a claim of Eleventh Amendment immunity in Verizon Maryland, Inc. v. Public Service Commission of Maryland, 535 U.S. 635 (2002):

> Whether the Commission waived its immunity is another question we need not decide, because . . . even absent waiver, Verizon may proceed against the individual commissioners in their official capacities pursuant to the doctrine of Ex parte Young, . . . In determining whether the doctrine of Ex parte Young avoids an Eleventh Amendment bar to suit, a court need only conduct a "straightforward inquiry into whether [the] complaint alleges an ongoing violation of federal law and seeks relief properly characterized as prospective."

Id. at 645 (citations omitted).

The applicability of Ex parte Young to Xechem's claim of incorrect inventorship was not raised on this appeal. Although Xechem states that Dr. Andersson violated federal law in averring that he is the sole inventor, neither he nor any other employee or agent of the state was sued individually in his official capacity. I express no view as to whether Young offers a path to relief on the issue here presented; this aspect is not resolved by this dismissal on the pleadings.

A Continuing Concern

The circumstances of this case illustrate that when a state is charged with contravention of federal law in a way that directly affects private property, and if no remedy is indeed available within the state's tribunals -- whether by the state's invocation of immunity or by federal preemption of the cause of action -- there can arise an affront to the fundamentals of due process. Respect for the principles of federalism does not automatically immunize the state from due process considerations. The Court in Florida Prepaid kept this door ajar. I write to the same purpose, for there is an increasing urgency, as the states enter the private competitive arena governed by the laws of intellectual property, to establish fair relationships and just recourse.

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

XECHEM INTERNATIONAL, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION
	§	NO. H-02-1013
	§	
THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER AND BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,	§	
	§	
Defendants.	§	

[Entered March 19, 2003]

FINAL JUDGMENT

For the reasons set forth in the separate Memorandum and Order-signed this day, it is

ORDERED and ADJUDGED that Plaintiff Xechem International, Inc. take nothing on its claims against Defendants The University of Texas M.D. Anderson Cancer Center and Board of Regents of the University of Texas System, and Plaintiff's claims are DISMISSED for failure to state a claim upon which relief may be granted.

This is a FINAL JUDGMENT.

The Clerk will enter this Order, providing a correct copy to all counsel of record.

SIGNED at Houston, Texas, on this 19TH day of March, 2003.

/s/ Ewing Werlein, Jr.
EWING WERLEIN, JR.
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

XECHEM INTERNATIONAL, INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION
	§	NO. H-02-1013
	§	
THE UNIVERSITY OF TEXAS M.D. ANDERSON CANCER CENTER AND BOARD OF REGENTS OF THE UNIVERSITY OF TEXAS SYSTEM,	§	
	§	
Defendants.	§	

[Entered March 19, 2003]

MEMORANDUM AND ORDER

Pending is Defendants' Amended Renewed Motion to Dismiss (Document No. 52).[1] After carefully considering the motion, response, reply, and applicable law, the Court concludes that the motion should be granted.

I. Background

This is a lawsuit for breach of contract, promissory estoppel, fraud, wrongful termination, impairment of contract, and declaratory judgment. Plaintiff also asserts a

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[1] Also pending is Defendants' Renewed Motion to Dismiss (Document No. 45). That motion is DENIED as moot.

cause of action for correction of inventorship pursuant to 35 U.S.C. § 256.

Paclitaxel is a well-known anti-tumor agent that has been approved by the Food and Drug Administration ("FDA") for the treatment of ovarian and breast cancer. Currently, it is available for humans in only one formulation approved by the FDA known as Taxol by Bristol Myers-Squibb Co. Taxol contains paclitaxel that is stabilized in ethanol and Cremophor El, which is used as a drug carrier to overcome poor water solubility problems associated with paclitaxel. Cremophor El is a trade name for a polyoxiethylated castor oil product that is considered highly toxic, is a suspected carcinogen, and makes paclitaxel hard to administer in that, among other things, it easily dissolves plasticizers from PVC-based infusion bags.

Plaintiff Xechem International, Inc. ("Xechem") is a bio-pharmaceutical company and Defendants The University of Texas M.D. Anderson Cancer Center ("MDA") and Board of Regents of the University of Texas System ("UT") are branches of the University of Texas, an agency of the State of Texas. In 1995, Xechem's President and CEO, Ramesch C. Pandey, Ph. D. ("Dr. Pandey"), contacted Roje S. Anderson, M.D., Ph.D. ("Dr. Anderson") at MDA, allegedly to discuss Dr. Pandey's interest in developing a new non-toxic formulation of paclitaxel. After several telephone conversations and meetings between Dr. Pandey and Dr. Anderson concerning the development of the new formulation, Xechem and Defendants entered into a sponsored laboratory study agreement (the "Sponsored Study Agreement") to develop or reduce to practice a clinically useful formulation of paclitaxel that would contain dimethylacetamide ("DMA") instead of Cremophor El as a drug carrier for the paclitaxel. The parties hoped that by creating a DMA-based paclitaxel, the complications associated with using Cremophor El as a drug carrier would

be eliminated and an alternative to Taxol would become available. All funding for the Sponsored Study Agreement as well as the paclitaxel used to develop the new formulation was allegedly provided by Xechem.

While the development of the new drug was underway, Xechem allegedly prepared a United States patent application for the new paclitaxel formulation. The application described and claimed the new DMA-based paclitaxel injectable formulation as well as the concept of a clinically useful DMA-based paclitaxel analog or derivative formulation. Before filing the application, Xechem allegedly forwarded the application to MDA, UT, and Dr. Anderson together with a declaration of inventorship naming both Dr. Pandey of Xechem and Dr. Anderson of MDA as co-inventors of the new drug. Unbeknownst to Xechem, however, MDA and UT allegedly commissioned the preparation and filing of a different United States patent application describing and claiming the same DMA-based paclitaxel formulation and analog claimed in Xechem's application, but naming Dr. Anderson as the sole inventor of the drug. Based on the second application, the United States Patent Office issued patent number 5,877,205 entitled Parenteral Paclitaxel Injectable Non-Toxic Formulation in 1999, and patent number 6,107,333 entitled Parenteral Paclitaxel in a Stable Non-Toxic Formulation in 2000 (collectively referred to as the ""205 and '333 Patents"). Both patents were assigned to UT and named Dr. Anderson as the sole inventor of the DMA-based paclitaxel formulation.

In 1997, before the issuance of the '205 and '333 Patents, but after the parties entered into the Sponsored Study Agreement, Xechem, MDA, and UT entered into a patent and technology license agreement (the "Agreement"), wherein Xechem was granted a royalty-bearing, exclusive worldwide license to manufacture and/or sell the new paclitaxel formulation. In 2000, after the '205 Patent was

issued, Defendants forwarded a letter to Xechem's counsel seeking both to terminate the Agreement pursuant to the commercialization and obligation clause of the Agreement and to offer Xechem a counter proposal.[2] Xechem rejected the counter proposal as well as Defendants' claim that the Agreement should be terminated. Thereafter, Defendants served a second letter upon Xechem's counsel terminating the Agreement pursuant to section 13.3 of the Agreement, which provides for automatic termination in the event of Xechem's bankruptcy or insolvency. According to Defendants, Xechem became insolvent as of December 1998 and as such, the Agreement automatically terminated on that date.

Approximately a month after receiving Defendants' termination letter, Xechem filed the instant suit.[3] Xechem alleges that the termination of the Agreement was without cause and seeks to reinstate the Agreement to continue its

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[2] What the counter proposal consisted of is unclear from the pleadings.

[3] The lawsuit was filed in the United States District Court District of New Jersey. While the case was pending in New Jersey, Defendants filed a Motion to Dismiss Xechem's Second Amended Complaint for lack of federal jurisdiction, lack of personal jurisdiction failure to state a claim upon which relief may be granted and improper venue. Alternatively, Defendants moved to transfer venue to the Southern District of Texas. The New Jersey court denied Defendants' Motion to Dismiss on grounds of personal jurisdiction and improper venue, but agreed that venue was more properly laid in this Court. By order entered February 21, 2002, the case was transferred to the Southern District of Texas. (Document No. 34). In light of the transfer, the New Jersey court declined to consider Defendants' challenge based on Eleventh Amendment Immunity grounds.

worldwide license to manufacture and/or sell the new paclitaxel formulation. Xechem further seeks a declaratory judgment stating that Xechem is not infringing upon the '205 and '333 Patents and to award damages for money it would have received under the Agreement had it not been terminated.

Xechem alleges that after receiving Defendants' letter of termination in 2000, it learned that the inventorship of the '205 and '333 Patents is incorrect in that it names Dr. Anderson as the sole inventor of the new paclitaxel formulation. According to Xechem, Dr. Anderson did not conceive or contribute to the subject matter recited in the claims of the '205 and '333 Patents, but only developed a commercial application for the new formulation. Xechem asserts that it was Dr. Pandey together with Elias J. Anaissie, M.D. ("Dr. Anaissie") and Luben K. Yankov, M.D. ("Dr. Yankov"), who conceived and invented the new formulation for the anti-cancer medication.

Pursuant to 35 U.S.C. § 256, Xechem requests that the Court determine the correct inventorship of the '205 and '333 Patents and that it correct the Patents either by adding Dr. Pandey and/or Dr. Yankov and/or Dr. Anaissie as joint inventors, or alternatively, by removing Dr. Anderson as an inventor and adding in place thereof Dr. Pandey and/or Dr. Yankov and/or Dr. Anaissie as joint inventors. Xechem further requests that the Court issue an order directing the Commissioner of Patents and Trademarks to correct the inventorship of the '205 and '333 Patents accordingly. Finally, Xechem seeks relief under several state causes of action including breach of contract, fraud, promissory estoppel, wrongful termination, impairment of contract, and declaratory judgment that Xechem's performance under the Agreement is excused.

Defendants move to dismiss Xechem's claims based on Eleventh Amendment immunity. They contend that as arms of the State, they enjoy sovereign immunity and cannot be sued in federal court. Xechem disputes Defendants' contention that Eleventh Amendment immunity bars Xechem's claims for declaration of non-infringement and for correction of inventorship under 35 U.S.C. § 256. Xechem concedes, however, that sovereign immunity bars its state law claims.[4] Given Xechem's concession, the Court will grant MDA's and UT's Motion to Dismiss Xechem's state law claims and will confine its analysis of Eleventh Amendment immunity to Xechem's remaining claims. The issues remaining are: Does Eleventh Amendment immunity bar Xechem's claims for declaration of non-infringement and for determination and correction of inventorship pursuant to 35 U.S.C. § 256, and have UT and MDA voluntarily waived their Eleventh Amendment immunity by voluntarily applying for and obtaining a United States patent from the United States Patent Office and accepting all benefits of United States patent laws?

II. Standard for Rule 12(b)(6)

Rule 12(b)(6) authorizes the dismissal of a claim for "failure to state a claim upon which relief can be granted." FED. R. CIV. P. 12(b)(6). In considering a motion to dismiss under Rule 12(b)(6), a court may not look beyond the face of the pleadings. Classroom Teachers of Dallas v. Dallas Indep. Sch. Dist., 164 F. Supp. 2d 839, 845 (N.D. Tex. 2001). Moreover, a district court must liberally construe the allegations in the complaint in favor of the plaintiff and must accept as true all well-pleaded facts in the complaint. Lowrey v. Tex. A & M Univ. Sys., 117 F.3d 242, 247 (5th Cir. 1997).

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[4] Xechem's counsel made this concession during the Rule 16 Scheduling Conference held on December 13, 2002.

Dismissal of a claim is improper unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief. Collins v. Morgan Stanley Dean Witter, 224 F.3d 496, 498 (5th Cir. 2000), "A plaintiff, however, must plead specific facts, not mere conclusory allegations, to avoid dismissal." Classroom Teachers of Dallas, 164 F. Supp. 2d at 845. "A motion to dismiss under rule 12(b)(6) 'is viewed with disfavor and is rarely granted.'" Collins, 224 F.3d at 498 (quoting Kaiser Aluminum & Chem. Sales v. Avondale Shipyards, 677 F.2d 1045, 1050 (5th Cir. 1982)).

III. Discussion

The Eleventh Amendment provides

> The Judicial power of the United States shall not be construed to extend to any suit in law or equity, commenced or prosecuted against one of the United States by Citizens of another State, or by Citizens or Subjects of any Foreign State.

U.S. CONST. amend. XI. The amendment recognizes that each State is a sovereign entity in our federal system. Seminole Tribe of Fla. v. Fla., 116 S. Ct. 1114, 1122 (1996). As such, a State is immune from suit in federal court regardless of whether the suit is based on diversity or federal question jurisdiction and regardless of whether the suit is filed against the State by one of its own citizens or by a citizen of another State. Atascadero State Hosp. V. Scanlon, 105 S. Ct. 3142, 3145 (1985); *see also* Seminole Tribe, 116 S. Ct. at 1122.

Sovereign immunity, however, is not absolute. Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 119 S. Ct. 2219, 2223 (1999). Under the Eleventh Amendment, a State may be sued in federal court if the State

expressly waives its sovereign immunity, its immunity is properly abrogated by Congress pursuant to § 5 of the Fourteenth Amendment, or the suit falls within the exception recognized for certain suits seeking declaratory and injunctive relief against state officers in their individual capacities. Atascadero, 105 S. Ct, at 3145; Ex Parte Young,. 28 S. Ct. 441, 454 (1908); Ysleta del Sur Pueblo v. Laney, 199 F.3d 281, 285 (5th Cir. 2000). "[B]ecause the Eleventh Amendment implicates the fundamental constitutional balance between the Federal Government and the States, [the Supreme Court] consistently has held that these exceptions apply only when certain specific conditions are met." Atascadero, 105 S. Ct. at 3145-46.

In this case, Xechem advances two arguments in support of its contention that the Eleventh Amendment does not bar its claims.[5] First, Xechem argues that the Eleventh Amendment does not preclude a suit against a State agency for correction of inventorship under § 256. Second, Xechem alleges that UT and MDA expressly waived their Eleventh Amendment immunity when they voluntarily accepted the benefits and protections of the '205 and '333 Patents.

With respect to the first contention, Xechem argues, without citing any authority to support its position, that the Eleventh Amendment is "inapplicable" to a claim in federal court under 35 U.S.C. § 256 because "inventorship contests by definition will lack the consent of all inventors." Pointing to the language of § 256 that the court "may order correction of the patent on notice and hearing of all parties concerned," Xechem contends that such notice requirements "do not

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[5] Xechem does not dispute that MDA and UT are arms of the State of Texas and that as such, they enjoy sovereign immunity under the Eleventh Amendment. Instead, Xechem argues that the Eleventh Amendment does not apply to this case.

implicate consent by the State," and hence, "do not implicate Eleventh Amendment immunity." Xechem further argues that because only Congress can grant patents, the correction of a patent is solely within the purview of Congress. Therefore, Xechem continues, Defendants' consent is not required to correct the inventorship of the '205 and '333 Patents.

Regardless of whether a defendant's consent is necessary to correct the inventorship of a patent, the Eleventh Amendment bars a party from suing a State in federal court if the State has not consented to the suit. Seminole Tribe, 116 S. Ct. at 1122. The relief sought against a State is irrelevant as to whether the suit is barred by the Eleventh Amendment. Id. at 1124. Moreover, Eleventh Amendment immunity not only protects a State from liability; it also protects a State from suit. This immunity from suit "does not exist solely in order to 'preven[t] federal-court judgments that must be paid out of a State's treasury.'" Id. at 1124 (quoting Hess v. Port Ruth. Trans-Hudson Corp., 115 S. Ct. 394, 404 (1994)) (alteration in original). "[I]t also serves to avoid "the indignity of subjecting a State to the coercive process of judicial tribunals at the instance of private parties.'" Id. (quoting Puerto Rico Aqueduct & Sewer Auth. v. Metcalf S Eddy, Inc., 113 S. Ct. 684, 689 (1993)).

It is uncontroverted that UT and MDA did not expressly consent to being sued by Xechem in this Court. Nonetheless, relying on Iowa State Univ. Research Found., Inc. v. Sperry Rand Corp., 444 F.2d 406 (4th Cir. 1971) (cited in Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1553 (Fed. Cir. 1997)), Xechem argues that by definition, inventorship contests lack the consent of all inventors and are not barred by the Eleventh Amendment. In Sperry Rand, however, the issue was not, as it is here, whether the Eleventh Amendment bars one's suit against a State agency in federal court to correct inventorship of a patent under §

256. Rather, the issue in Sperry Rand was whether a district court has the authority at all to hear a suit under § 256 and to correct the inventorship of a patent by adding the name of a joint-inventor over the named inventor's objections.

In deciding that issue, the Fourth Circuit Court of Appeals concluded that the Commissioner of Patents and Trademarks can correct innocent errors of misjoinder or nonjoinder in patent applications when all parties apply for relief, but that when parties contest the correction of the patent, relief for correction may, and must, be sought in federal court. See id, at 408-09 (noting that when correction of a patent is disputed, the correction can be made only be order of court). In reaching its conclusion, the court in Sperry Rand did not consider, and the parties never raised, the issue of Eleventh Amendment immunity.[6] As such, Sperry Rand is inapposite.

Xechem's claim under § 256 is somewhat similar to a claim for declaratory judgment, in which a plaintiff petitions for a resolution of a dispute or for a declaration of the rights of the parties. Likewise, in this case, a dispute has arisen regarding the true inventor of the "205 and '333 Patents. As such, not unlike a claim for declaratory judgment, Xechem is asking the Court to determine who are the true inventors of the '205 and '333 Patents and to correct the inventorship accordingly. Just as Eleventh Amendment immunity bars an action for declaratory judgment against a State in federal court, so the Eleventh Amendment also bars Xechem's claim for correction of inventorship under 35 U.S.C. § 256.

Xechem's second argument is that even if Eleventh Amendment immunity applies, UT and MDA constructively waived their immunity by accepting a federal patent.

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[6] Iowa State University Research Foundation, Inc., if an agency of the State of Iowa, intervened in the case and thereby waived any Eleventh Amendment immunity it may have enjoyed.

Xechem contends that in the Patent and Plant Protection Remedy Clarification Act passed in 1992 (the "Patent Remedy Act"), Congress clearly expressed its intent that a State waive its sovereign immunity upon its acceptance of a federal patent. Thus, Xechem alleges, when MDA and UT applied and obtained the '205 and '333 Patents, after the enactment of the Patent Remedy Act, they unequivocally and voluntarily waived their Eleventh Amendment immunity with respect to patent enforcement claims.

This argument is foreclosed by College Savings and Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank, 119 S. Ct. 2199 (1999). Congress in 1992, enacted and codified the Patent Remedy Act, 35 U.S.C. §§ 271(h) and 296. Prior to its enactment, "the patent laws stated only that 'whoever' without authority made, used, or sold a patented invention infringed the patent." Florida Prepaid, 119 S. Ct. at 2203 (citing 35 U.S.C. § 271 (a)). The Patent Remedy Act amended the patent code by defining the term "whoever." Section 271(h) provides

> (h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

35 U.S.C. § 271 (h). Similarly, § 296 provides that

> (a) In general.-Any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity, shall not be immune,

> under the eleventh amendment of the Constitution of the United States or under any other doctrine of sovereign immunity, from suit in Federal court by any person, including any governmental or nongovernmental entity, for infringement of a patent under section 271, or for any other violation under this title.

35 U.S.C. § 296. By these two amendments, Congress expressly sought to abrogate the States' Eleventh Amendment immunity and to subject States to liability in federal court for infringement or for other violations of the patent laws. See Florida Prepaid, 119 S. Ct. at 2205 ("We agree with the parties and the Federal Circuit that in enacting the Patent Remedy Act, Congress has made its intention to abrogate the States' immunity unmistakably clear in the language of the statute.") (internal citations omitted).

The Supreme Court held, however, that these provisions of the Patent Remedy Act were not authorized by any of Congress's three claimed sources of constitutional authority; the Commerce Clause, the Patent Clause, and § 5 of the Fourteenth Amendment. Id. at 2205, 2210-11. First, citing its decision in Seminole Tribe, the Court reiterated that Congress does not have the power to abrogate Eleventh

Amendment immunity pursuant to its Article I powers.[7] Id. at 2205. With respect to Congress's attempt to abrogate immunity under the Fourteenth Amendment, the Court found that while Congress does have the power under that amendment to abrogate sovereign immunity, Congress had overreached its § 5 power by enacting, the Patent Remedy Act, 35 U.S.C. §§ 271(h) and 296, and purporting to subject States to private lawsuits. "Id. at 2210-11. The Court found that "the Patent Remedy Act [did] not respond to a history of 'widespread and persisting deprivation of constitutional rights' of the sort Congress has faced in enacting proper prophylactic § 5 legislation." Id. at 2210 (quoting City of Boerne v. Flores, 117 S. Ct. 2157, 2167 (1997)}. Consequently, the Court struck down as unconstitutional §§ 271(h) and 296 of the Patent Remedy Act. Id. at 2210-11.

Notwithstanding the decision in Florida Prepaid, Xechem now relies on the same provisions of the Patent

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[7] Although the Supreme Court previously had held in Pa. v. Union Gas Co., 109 S. Ct. 2273, 2286 (1996), that Congress has the power to abrogate Eleventh Amendment immunity pursuant to the Commerce Clause, the Court in Seminole Tribe, overruled Union Gas, holding that Congress does not have the power to abrogate a State's Eleventh Amendment immunity pursuant to its Article I powers, including the Commerce Clause. Seminole Tribe, 116 S. Ct. at 1128. The Court held that Congress can abrogate sovereign immunity only pursuant to § 5 of the Fourteenth Amendment. Id. at 1128. The Court reasoned that the Fourteenth Amendment, unlike the Commerce Clause, was adopted after the Eleventh Amendment and the ratification of the Constitution. Id. Consequently, the Court explained, the adoption of the Fourteenth Amendment, unlike the Commerce Clause, "operated to alter the pre-existing balance between state and federal power achieved by Article III and the Eleventh Amendment." Id.

Remedy Act that have been held unconstitutional to advance its position that those provisions, although expressly passed in a failed attempt to *abrogate* sovereign immunity, also constitute a *waiver* of sovereign immunity because the provisions expressly condition a State's acceptance of a patent upon the State's consent to suit in federal court. Xechem's constructive waiver argument, however, is foreclosed by College Savings, wherein the Supreme Court found that constitutional immunity may not be constructively waived.

On the same day it handed down the Florida Prepaid decision, the Supreme Court decided College Savings. The question in College Savings was whether the provisions of the Trademark Remedy Clarification Act ("TRCA"), which are nearly identical to §§ 271(h) and 296 of the Patent Remedy Act[8], allowed a "suit against [the respondent Florida Prepaid] for its alleged misrepresentation of its own product—either because the TRCA effects a constitutionally permissible abrogation of state sovereign immunity, or because (as Xechem alleges here] the TRCA operates as an invitation to waiver of such immunity which is automatically accepted by a State's engaging in the activities regulated by the Lanham Act." Coll. Sav., 119 S. Ct. at 2222.

College Savings Bank, the petitioner in College Savings, argued that the TRCA had constitutionally been passed pursuant to § 5 of the Fourteenth Amendment in an attempt to abrogate sovereign immunity. Id. at 2224. After analyzing College Savings's abrogation argument, however, the Court found that the right to be free from a business competitor's false advertising about its own product and to be secure in one's business interests are not property rights protected by the Fourteenth Amendment. . Id. at 2225.

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[8] *Compare* Florida Prepaid. 119 S. Ct. at 2203, *with* Coll. Sav. 119 S. Ct. at 2223.

Accordingly, the Court found that § 5 of the Fourteenth Amendment did not lend support to College Saving's abrogation argument. Id.

Finding no abrogation, the Court turned next to College Savings's alternative argument that Florida Prepaid's sovereign immunity, though not abrogated, was constructively waived. Based on Parden v. Terminal Railway of Alabama Docks Dep't, 84 S. Ct. 1207 (1964), College Savings argued, as Xechem similarly does here, that "Florida Prepaid had [constructively] waived its immunity from Lanham Act suits by engaging in the interstate marketing and administration of its program after the TRCA made clear that such activity would subject Florida Prepaid to suit."[9] Id. at 2224. In rejecting College Savings's

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[9] In Parden, the Supreme Court "permitted employees of a railroad owned and operated by Alabama to bring an action under the Federal Employers' Liability Act (FELA) against their employer." Coll. Sav., 119 S. Ct. at 2226. "Despite the absence of any provision in the statute specifically referring to the States, [the Court] held that the Act authorized suits against the States by virtue of its general provision subjecting to suit '[e]very common carrier by railroad . . . engaging in commerce between . . . the several States' . . . ." Id. (alteration in original). The Court found that

> By enacting the [FELA] . . . Congress conditioned the right to operate a railroad in interstate commerce upon amenability to suit in federal court as provided by the Act; by thereafter operating a railroad in interstate commerce, Alabama must be taken to have accepted that condition and thus to have consented to suit

Parden, 84 S. Ct. at 1213.

argument, the Court overruled Parden, finding that "the constructive-waiver experiment of [that case] was ill conceived." Id. at 2228.

The Court first observed that Parden is inconsistent with the requirement that a State's express waiver of immunity be unequivocal. Id. Given such a requirement, the Court noted that "there is little reason to assume actual consent based upon the State's mere presence in a field subject to congressional regulation." Id. In addition, the Court found that "[r]ecognizing a congressional power to exact constructive waivers, of sovereign immunity through the exercise of Article I powers would ... as a practical matter, permit Congress to circumvent the antiabrogation holding of Seminole Tribe." Id. at 2229. Accordingly, the Court found that College Savings could not, as Xechem attempts to do here, advance its claim of waiver by invoking the same provisions that were enacted in a failed attempt to abrogate sovereign immunity. *See* id. at 2229-30 ("As further evidence that constructive waiver is little more than abrogation under another name, consider the revealing facts of this case: The statutory provision relied upon to demonstrate that Florida constructively waived its sovereign immunity is the very same provision that purported to abrogate it.").

College Savings therefore makes clear that Eleventh Amendment immunity may not be constructively waived. Xechem nonetheless argues that constructive waiver may still exist when Congress bestows a gift or gratuity upon a State on the condition that the State consent to suit in federal court and the State voluntarily accepts the gift. Because Congress through the Patent Remedy Act, 35 U.S.C. §§ 271(h) and 296, expressly conditioned the receipt of a patent upon the State's consent to waive immunity, Xechem argues, MDA and UT did waive their sovereign immunity when they applied for and accepted the '205 and '333

Patents. To support its position, Xechem cites New Star Lasers, Inc. v. Regents of Univ. of California, 63 F. Supp. 2d 1240 (E.D. Cal. 1999).10

In New Star Lasers, the plaintiff New Star Lasers ("New Star") sued The Regents of the University of California (the "University") in federal court for a declaration of non-infringement by reason of patent invalidity. New Star Lasers, 63 F. Supp. 2d at 1241. The University moved to dismiss New Star's claim based on Eleventh Amendment immunity. Id. In considering the University's motion, the district court concluded that a patent constitutes a gift or gratuity bestowed by the federal government and that pursuant to College Savings, "if Congress has conditioned [the receipt of a patent] on a waiver of Eleventh Amendment immunity to a declaratory suit, then Congress has acted permissibly." Id. at 1244. Concluding that the Patent Remedy Act constitutes a clear

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10 Xechem also cites AT&T Communications v. BellSouth Telecommunications, Inc., 238 F.3d 636 (5th Cir. 2001) for support. In that case, the Fifth Circuit Court of Appeals found that the Louisiana Public Service Commission constructively waived its sovereign immunity by accepting Congress's invitation to regulate local telecommunication competition under the Telecommunication Act of 1996. AT&T Communications, 238 F.3d at 639. AT&T Communications, however, is distinguishable from the present case. First, the statute under consideration in AT&T Communications is significantly different from the statute in this case. Second, the alleged gratuity in that case, i.e. the regulation of local telecommunication competition, is different from the alleged gratuity in this case, i.e. the issuance of a patent. Finally, the parties in AT&T Communications did not, as Xechem does here, advance their position of waiver by relying on a statute that was passed in an unconstitutional attempt to abrogate sovereign immunity.

and unmistakable requirement of waiver, the district court in New Lasers denied the University's motion to dismiss and held that the University "presumably knew of the accompanying waiver [in the Patent Remedy Act] when [it] acquired the patent in question . . . ." Id. at 1245.

The holding in New Star Lasers is not persuasive. Assuming without deciding that a patent constitutes a gift or a gratuity bestowed upon a State, this does not lead to the conclusion that the Patent Remedy Act served to extract a waiver of Eleventh Amendment immunity from UT and MDA. While it is true that the Supreme Court in College Savings distinguished as fundamentally different a situation in which Congress requires waiver of immunity when it confers a specific gift or gratuity on a State in exchange for giving the State its consent to take actions it otherwise could not lawfully take, Coll. Sav., 119 S. Ct. at 2227 n.2, 2231, the Supreme Court has emphasized that to find waiver, Congress must manifest a clear intent to *condition* participation in a federal program upon a State's *consent* to waive its constitutional immunity. Atascadero, 105 S. Ct. at 3149-50. Congress may not extract a constructive waiver from a State without plainly stating its intention to *condition* the giving of a gratuity upon the State's *consent* to waive immunity.

The provision of the Patent Remedy Act that Xechem relies upon does not manifest a clear intent on the part of Congress to condition the issuance of a patent to a State upon the State's consent to waive its constitutional immunity. Section 271(h), upon which Xechem's waiver arguments are premised, provides:

> (h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a

> State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

35 U.S.C. § 271 (h). Section 271 (h) by its express language does not condition the issuance of a patent to a State upon a State's consent to waive its sovereign immunity under the Eleventh Amendment, and this Court cannot graft upon the statute such a requirement.[11]

This lack of express conditional language in the Patent Remedy Act is not surprising given that the Patent Remedy Act was passed in an attempt to *abrogate* the sovereign immunity of *unconsenting* States rather than to condition the issuance of patents upon express *waivers* of Eleventh Amendment immunity by *consenting* States. See Florida Prepaid, 119 S. Ct. at 2205 (explaining that the Patent Remedy Act was passed in an attempt to abrogate sovereign immunity). Abrogation and waiver, though somewhat interrelated, are not interchangeable terms. Abrogation refers to Congress's authority to subject *unconsenting* States to suit in federal court, while *waiver* refers to a State's *express consent* to federal jurisdiction. *See* Atascadero, 105 S. Ct. at 3149; *see also* Welch v. Tex. Dep't of Highways & Public Transp., 107 S. Ct. 2941, 2946 (1987) (explaining that Congress can abrogate Eleventh Amendment immunity without the consent of States).

Xechem argues that finding immunity under the circumstances of this case could lead to inequitable results. States, for example, could infringe on a patent without the

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[11] Although Xechem does not cite § 296 for support, the same can be said with respect to that section. *See* 35 U.S.C. § 296.

fear of facing repercussions for their actions in federal court; they could threaten legal action for infringement against a party without the fear of being sued in federal court for a declaration of invalidity; or, as alleged in this case, they could omit the name of a co-inventor from a patent application without being subject to a correction of inventorship action pursuant to 35 U.S.C. § 256. Admittedly, these are all undesirable results.[12] This Court, however, must apply the Constitution and laws as they are written and with due regard for the controlling decisions of the Supreme Court.

IV. Order

For the reasons set forth, it is hereby

ORDERED that Defendants The University of Texas M.D. Anderson Cancer Center's and The Board of Regents of the University of Texas System's Amended Renewed Motion to Dismiss (Document No. 52) is GRANTED, and Plaintiff Xechem International, Inc.'s claims are dismissed for failure to state a claim upon which relief may be granted.

The Clerk will enter this Order and send copies to all counsel of record.

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[12] After College Savings and Florida Prepaid were decided, legislation was introduced in the Senate that would condition the issuance of a patent upon a State's waiver of Eleventh Amendment immunity. *See* Intellectual Property Protection Restoration Act of 1999, S. 1835, 106th Cong. (1999), available st http:// copyright.qov/leqislation/archive (last visited Feb. 19, 2003). This bill, unlike the Patent Remedy Act, expressly proposed to condition the issuance of a patent on a State's waiver of sovereign immunity. *See* id. The Court does not know if similar bills have been introduced in the current Congress.

SIGNED at Houston, Texas, on this 19TH day of March, 2003.

/s/ Ewing Werlein, Jr.
EWING WERLEIN, JR.
UNITED STATES DISTRICT JUDGE